

behalf of the recipient's clients, such legal assistance shall be treated in the same manner as court appointments under paragraphs (a)(1), (a) (3), (b) and (c) of this section.

Dated: January 10, 1995.

Victor M. Fortuno,
General Counsel.

[FR Doc. 95-1072 Filed 1-13-95; 8:45 am]

BILLING CODE 7050-01-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket No. 50018; RIN 2105-AC20]

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Procedures for Non-Evidential Alcohol Screening Devices

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: When the Department of Transportation published its final alcohol testing rules in February 1994, it said that if non-evidential screening devices were approved, the devices could be used for screening tests in DOT-mandated alcohol testing programs. Several such devices have now met precision and accuracy requirements. This proposed rule is intended to establish procedures for the use of these devices.

DATES: Comments should be received by February 16, 1995. Late-filed comments will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Albert Alvarez, Director, Department of Transportation Office of Drug Enforcement and Program Compliance, 400 7th Street, S.W., Washington D.C., 20590, Room 9404, 202-366-3784; or Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, 400 7th Street, S.W., Room 10424, 202-366-9306.

SUPPLEMENTARY INFORMATION: When the Department published its final alcohol testing rules in February 1994 (59 FR 7302 *et seq.*, February 15, 1994), the Department established breath testing, using evidential breath testing devices (EBTs), as the method to be used. However, in response to comments requesting additional flexibility in testing methods, the Department said that

NHTSA [the National Highway Traffic Safety Administration] will develop model specifications (using precision and accuracy criteria), evaluate additional screening

devices against them, and periodically publish a conforming products list of those additional screening devices (not exclusively breath testing devices) that meet the model specifications. . . . Please note that the Department will also have to undertake separate rulemaking proceedings to establish procedures for the use of any devices after they are approved. (Id. at 7316).

NHTSA published model specifications, tested several screening devices and, on December 2, 1994, published a conforming products list (CPL) including four non-evidential breath testing devices and one saliva testing device. As noted in the February 15 common preamble cited above, while NHTSA has now determined that these devices meet the model specifications, their use in DOT-mandated alcohol testing programs would be authorized only in accordance with these proposed procedures (just as EBTs are authorized for use only in accordance with existing Part 40 procedures). Until these proposed procedures are final and in effect, employers are not authorized to use the non-evidential screening devices.

These devices could be used under final procedural rules, it should be emphasized, only for alcohol *screening* tests. Confirmation tests must be performed on EBTs, within 20 minutes of the screening test, as provided in existing 49 CFR 40.65(b). The Department is aware that increasing this interval for situations in which non-evidential devices are used could provide additional flexibility to employers, by increasing the distance that a non-evidential screening test could be conducted away from a confirmation EBT. However, as noted in the preamble to the February 15, 1994, final Part 40 rule, conducting the confirmation test within a brief time from the screening test is important in order to prevent metabolization of alcohol over time from negating what otherwise would be "positive" test results. This is no less true in a case where the screening test is conducted on a non-evidential device than where the screening test is conducted on an EBT. For this reason, the Department is not proposing to increase this interval, though we seek comment on the degree to which an increased interval between screening and confirmation tests could increase the utility of non-evidential devices, without concomitant loss of otherwise positive tests.

In drafting these proposed procedures, the Department used the model of its existing alcohol testing procedures, with modifications appropriate to the different devices involved. This makes the proposed

procedures simple and achieves the flexibility that is the goal of using non-evidential devices.

Proposed § 40.91 simply states that non-evidential devices, approved by NHTSA, can be used for screening but not for confirmation tests. Proposed § 40.93 addresses the more complex issue of who may act as a screening test technician (STT), with what degree of training. First, any BAT meeting the requirements of the existing Part 40 may act as an STT, provided that the individual has demonstrated proficiency on the particular non-evidential device he or she will use (by completing a "Unit VIII" of the DOT model BAT course, or similar section of a DOT-approved equivalent course, specific to the particular device).

There may be some individuals who will act as STTs who do not act as BATs. These individuals would conduct only screening tests using non-evidential devices and would never use EBTs or conduct confirmation tests. The Department is adapting its model BAT course for use in training such persons. We anticipate that this course will be a substantially shorter version of the BAT course, focusing on screening procedures only. The Department will make this course outline available by the time a final rule based on this proposal is published: Someone who successfully completes this course could act as an STT, under paragraph (b) of this section. The remainder of the section, with respect to additional training, documentation of training, and other subjects, parallels existing Part 40.

Proposed § 40.97 concerns locations for screening tests. Location requirements are the same as the parallel section in the existing Part 40 alcohol procedures. Proposed § 40.99 provides that like employers using an EBT without the features needed for confirmation tests, employers using non-evidential *breath* testing devices would use the same form as, and a log book like, those cited in § 40.59 of the existing alcohol testing procedures. A slightly modified form is described at the end of the proposed rule text. The Department seeks comment on whether it would be better to take this approach or to attempt to modify the existing alcohol testing form to encompass non-breath based testing.

For employers using non-evidential breath testing, proposed § 40.101 provides that the STT or BAT would follow essentially the same procedures as are followed for a screening test using an EBT. The technology and testing process using a non-evidential breath testing device and an EBT are similar enough that the existing procedures can

be used as they are. For purposes of these proposed procedures, we view the results displayed on non-evidential breath devices as equivalent to those displayed on EBTs, even if the mode of display is different. We seek comment on whether any greater specificity concerning the display of results on non-evidential breath testing devices is needed.

Saliva testing devices are another matter, since they use a different technology and require different procedures. Proposed § 40.101(d) spells out these procedures. After opening the package containing the device, the STT lets the employee choose whether to use the swab him- or herself or whether to have the STT use the swab. For the sake of hygiene, the STT would wear a surgical glove or other adequate sanitary hand protection whenever the STT performs this task. This is advisable both from the point of view of the STT and the employee. Such a requirement is likely to make all parties more accepting of this testing method, and the Department proposes to require it for this reason. The Department is informed by the Occupational Health and Safety Administration (OSHA) that its rules concerning bloodborne pathogens (29 CFR 1910.1030) do not apply to saliva testing of this sort, since those rules do not designate saliva as a "potentially infectious material" except in the context of dental procedures. However, employers should check applicable state or local laws to determine if they impose any additional requirements. These same comments apply to the disposal of saliva test materials (see § 40.101(f)).

The point of the swabbing exercise is to get the absorbent end of the swab completely saturated so that it will activate the device. Once the swab is saturated, the STT places it into the receptacle on the device, maintaining pressure on the device until the device is activated. The manufacturer's instructions will describe how the STT is to know whether the device has been activated. For example, the device that is now on the NHTSA CPL has an indicator spot that turns a particular color when the device is activated.

There are two main types of problems that can happen in this process. First, the process of using the device can miscarry (e.g., the swab breaks or falls to the floor). In this case, the STT is instructed to start the process over with a new device and swab. In this case, the STT would note the occurrence in the "remarks" section of the form. The Department seeks comments on whether it would be advisable to use a new form in this situation. Second, the process

can work correctly, but the device does not activate. In this case, the STT also begins the process anew, but the STT, rather than the employee, must use the swab (this is because insufficient saturation of the swab is a common reason for the failure of the device to activate).

Once the device activates, the STT reads the result. This reading must take place within the time frame specified in the manufacturer's instructions for the device (e.g., 2-15 minutes in the case of the saliva device now on the CPL). The instructions will also indicate the manner in which the reading is made (e.g., a numerical scale or other indication that there is an alcohol concentration of .02 or greater). Following the reading of the result, the STT proceeds in the same manner as does the BAT in a case when an EBT not having the features necessary for confirmation tests is used. The Department is proposing to amend the procedures for this situation, both where an EBT and where a non-evidential screening device is used. Under this proposal, following a screening test showing a result of .02 or greater, the employee would have to be advised against eating, drinking, etc.; would have to be advised against driving (as noted in Block 4 of the form); and would have to be under observation while going from the screening test site to the confirmation test site.

Refusals to test and incomplete tests (proposed § 40.103) are handled in a manner parallel to that of existing alcohol Part 40 procedures. There is also a parallel to existing alcohol Part 40's procedures for situations in which an adequate sample is not provided (§ 40.105). For non-evidential breath devices, the same "shy lung" procedures that are used with EBTs (see § 40.69) are employed. For saliva devices, in situations such as the apparent inability of the employee to saturate the swab sufficiently to activate the device, the STT would first conduct a new test, as provided in § 40.101. If the same thing happens on the new test, the STT makes a note in the "remarks" section of the form. The employer is then responsible for immediately conducting a breath test. Since an EBT must be available within 20 minutes in order to conduct a confirmation test, this approach appears workable. The Department seeks comment on whether the rule should specify that an EBT be used for this purpose, since going from a saliva device to a non-evidential breath test device to an EBT (if needed for confirmation) could unnecessarily lengthen the entire procedure, perhaps

resulting in the loss of what otherwise would be a positive test.

It is our understanding that individuals cannot voluntarily control the production of saliva. Consequently, there is no precise parallel to "shy lung" or "shy bladder" situations in the case of saliva testing, and refusals would occur only if the employee declined to permit the technician to use the swab or declined to take a subsequent breath test. A medical review, parallel to that provided in the urine and breath testing situations, appears unnecessary here.

Proposed § 40.107 is a brief list of "fatal flaws" in non-evidential screening tests. For saliva tests, these include results read in an untimely manner, use of a device past its designated shelf life, and the failure of the device to activate. Other fatal flaws are similar to those in the existing Part 40 alcohol testing procedures. The requirements concerning availability and disclosure of information about employees and maintenance and disclosure of records concerning STTs and non-evidential devices are also the same as those of existing Part 40 procedures.

Regulatory Analyses and Notices

This is not a significant rule under Executive Order 12866 or under the Department's Regulatory Policies and Procedures. It does not impose costs on regulated parties. It facilitates the use of devices that may increase flexibility, and decrease costs, for employers who choose to use them. There are not sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. To the extent that there is any such impact, it is expected to be a small favorable impact, since some small entities may be able to conduct screening tests at a lower cost.

List of Subjects in 49 CFR Part 40

Drug testing, Alcohol testing, Laboratories, Reporting and Recordkeeping requirements, Safety, Transportation.

Issued this 10th Day of January, 1995, at Washington, D.C.

Federico Peña,
Secretary of Transportation.

For the reasons set forth in the preamble, 49 CFR part 40 is proposed to be amended as follows:

1. The authority citation for part 40 continues to read as follows:

Authority: 49 U.S.C. 102,301,322; 49 U.S.C. app. 1301nt., app. 1434nt., app. 2717, app. 1618a.

§ 40.51 [Amended]

2. § 40.51(c) is proposed to be amended by adding the words "or non-evidential alcohol screening device" after the word "EBT."

3. A new § 40.63(h) is proposed to be added, to read as follows:

§ 40.63 Procedures for screening tests.

* * * * *

(h) If the confirmation test will be conducted at a different site from the screening test, the employer or its agent shall ensure that—

(1) The employee is advised against taking any of the actions mentioned in the first sentence of § 40.65(b) of this Part;

(2) The employee is advised that he or she must not drive, perform safety-sensitive duties, or operate heavy equipment, as noted in Block 4 of the alcohol testing form; and

(3) The employee is under observation of a BAT, STT, or other employer personnel while in transit from the screening test site to the confirmation test site.

4. A new Subpart D of Part 40 is proposed to be added, to read as follows:

Subpart D—Non-Evidential Alcohol Screening Tests

- 40.91 Authorization for use of non-evidential alcohol screening devices.
 40.93 The screening test technician.
 40.95 Quality assurance plans and manufacturers' instructions for non-evidential screening devices.
 40.97 Locations for non-evidential alcohol screening tests.
 40.99 Testing forms and log books.
 40.101 Screening test procedure.
 40.103 Refusals to test and uncompleted tests.
 40.105 Inability to provide an adequate sample.
 40.107 Invalid tests.
 40.109 Availability and disclosure of alcohol testing information about individual employees.
 40.111 Maintenance and disclosure of records concerning non-evidential alcohol screening test devices and screening test technicians.

Subpart D—Non-evidential alcohol screening devices**§ 40.91 Authorization for use of non-evidential alcohol screening devices.**

Non-evidential alcohol screening tests, performed using screening devices included by the National Highway Traffic Safety Administration on its conforming products list for non-evidential screening devices, may be used in lieu of EBTs to perform screening tests required by operating administrations' alcohol testing regulations. Non-evidential screening

devices may not be used for confirmation alcohol tests, which must be conducted using EBTs as provided in Subpart C of this Part.

§ 40.93 The screening test technician.

(a) Anyone meeting the requirements of this Part to be a BAT may act as a screening test technician (STT), provided that the individual has demonstrated proficiency in the operation of the non-evidential screening device he or she is using.

(b) Any other individual may act as an STT if he or she successfully completes a course of instruction concerning the procedures required by this Part for conducting alcohol screening tests. Only the Department of Transportation model course, or a course of instruction determined by the Department of Transportation's Office of Drug Enforcement and Program Compliance to be equivalent to it, may be used for this purpose.

(c) With respect to any non-evidential screening device involving changes, contrasts, or other readings that are indicated on the device in terms of color, STTs shall, in order to be regarded as proficient, be able to discern correctly these changes, contrasts or readings.

(d) The STT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that he or she will use.

(e) The employer or its agent shall document the training and proficiency of each STT it uses to test employees and maintain the documentation as provided in § 40.83.

(f) The provisions of § 40.51(b) and (c) of this Part apply to STTs as well as to BATs.

§ 40.95 Quality assurance plans and manufacturers' instructions for non-evidential screening devices.

(a) In order to be used for alcohol screening tests subject to this part, a non-evidential screening device shall have a DOT-approved quality assurance plan (QAP) developed by the manufacturer.

(1) The plan shall designate the method or methods to be used to perform quality control checks; the temperatures at which the non-evidential screening device shall be stored and used, as well as other environmental conditions (e.g., altitude, humidity) that may affect the performance of the device; and, where relevant, the shelf life of the device.

(2) The QAP shall prohibit the use of any device that does not pass the specified quality control checks or that has passed its expiration date.

(b) The manufacturers' instructions on or included in the package for each saliva testing device shall include directions on the proper use of the device, the time frame within reach the device must be read and indicate the manner in which the reading is made.

(c) The employer shall comply with the QAP and manufacturer's instructions for each non-evidential screening device it uses for alcohol screening tests subject to this Part.

§ 40.97 Locations for non-evidential alcohol screening tests.

(a) Locations for non-evidential alcohol screening tests shall meet the same requirements set forth for breath alcohol testing in § 40.57 of this Part.

(b) The STT shall supervise only one employee's use of a non-evidential screening device at a time. The STT shall not leave the alcohol testing location while the testing procedure for a given employee is in progress.

§ 40.99 Testing forms and log books.

(a) Employers using a non-evidential breath testing device shall use the alcohol testing form and log book as provided in § 40.59 and Appendix B of this Part for the screening test.

(b) Employers using a saliva screening device shall use the alcohol testing form found in Appendix C of this Part.

§ 40.101 Screening test procedure.

(a) The steps for preparation for testing shall be the same as provided for breath alcohol testing in § 40.61 of this Part.

(b) The STT shall complete Step 1 on the form required by § 40.99. The employee shall then complete Step 2 on the form, signing the certification. Refusal by the employee to sign this certification shall be regarded as a refusal to take the test.

(c) If the employer is using a non-evidential breath testing device, the STT shall follow the same steps outlined for screening tests using EBTs in § 40.63.

(d) If the employer is using a saliva testing device, the STT shall take the following steps:

(1) The STT shall check the expiration date of the saliva testing device, and shall not use a device at any time subsequent to the expiration date.

(2) The STT shall open an individually sealed package containing the device in the presence of the employee.

(3) The STT shall offer the employee the opportunity to use the swab. If the employee chooses to use the swab, the STT shall instruct the employee to insert the absorbent end of the swab into the employee's mouth, moving it

actively throughout the mouth for a sufficient time to ensure that it is completely saturated, as provided in the manufacturer's instructions for the device.

(4) If the employee chooses not to use the swab, or in all cases in which a new test is necessary because the device did not activate (see paragraph (d)(7) of this section), the STT shall insert the absorbent end of the swab into the employee's mouth, moving it actively throughout the mouth for a sufficient time to ensure that it is completely saturated, as provided in the manufacturer's instructions for the device. The STT shall wear a surgical glove or other adequate sanitary hand protection while doing so, consistent with applicable requirements.

(5) The STT shall place the device on a flat surface or otherwise in a position in which the swab can be firmly placed into the opening provided in the device for this purpose. The STT shall insert the swab into this opening and maintain firm pressure on the device until the device indicates that it is activated.

(6) If the procedures of paragraphs (d)(2)–(d)(4) of this section are not followed successfully (e.g., the swab breaks, the STT drops the swab on the floor or another surface, the swab is removed or falls from the device before the device is activated), the STT shall discard the device and swab and conduct a new test using a new device. The STT shall note in the remarks section of the form that the reason for the new test. In this case, the STT shall offer the employee the choice of using the swab himself or herself or having the STT use the swab. If the procedures of paragraphs (d)(2)–(d)(4) of this section are not followed successfully on the new test, the collection shall be terminated and an explanation provided in the remarks section of the form. A new test shall then be conducted, using breath testing.

(7) If the procedures of paragraphs (d)(2)–(d)(4) of this section are followed successfully, but the device is not activated, the STT shall discard the device and swab and conduct a new test, in the same manner as provided in paragraph (d)(6) of this section. In this case, the STT shall place the swab into the employee's mouth to collect saliva for the new test.

(8) The STT shall read the result displayed on the device within the time provided in the manufacturer's instructions for the device. The STT shall show the device and its reading to the employee and enter the result on the form.

(9) Devices, swabs, gloves and other materials used in saliva testing shall not

be reused, and shall be disposed of in a sanitary manner following their use, consistent with applicable requirements.

(e) In the case of any screening test performed under this section, the STT, after determining the alcohol concentration result, shall follow the applicable provisions of § 40.63 (e)(1)–(2), (f), (g), and (h). Following completion of the screening test, the STT shall date the form and sign the certification in Step 3 of the form.

§ 40.103 Refusals to test and uncompleted tests.

(a) Refusal by an employee to complete and sign the alcohol testing form required by § 40.99 (Step 2), to provide a breath or saliva sample, to provide an adequate amount of breath, or otherwise to cooperate in a way that prevents the completion of the testing process, shall be noted by the STT in the remarks section of the form. This constitutes a refusal to test. The testing process shall be terminated and the STT shall immediately notify the employer.

(b) If the screening test cannot be completed, or if an event occurs that would invalidate the test, the STT shall, if practicable, begin a new screening test, using a new testing form and, in the case of test using a saliva screening device, a new device.

§ 40.105 Inability to provide an adequate amount of breath or saliva.

(a) If an employee is unable to provide sufficient breath to complete a test on a non-evidential breath testing device, the procedures of § 40.69 apply.

(b) If an employee is unable to provide sufficient saliva to complete a test on a saliva screening device (e.g., the employee does not provide sufficient saliva to activate the device), the STT, as provided in § 40.101 of this Part, shall conduct a new test using a new device. If the employee refuses to complete the new test, the STT shall terminate testing and immediately inform the employer. This constitutes a refusal to test.

(c) If the new test is completed, but there is an insufficient amount of saliva to activate the device, STT shall immediately inform the employer, which shall immediately cause a breath alcohol test to be administered to the employee.

§ 40.107 Invalid tests.

An alcohol test using a non-evidential screening device shall be invalid under the following circumstances:

(a) With respect to a test conducted on a saliva device—

(1) The result is not read within the time frame specified by the

manufacturer's instructions for the device.

(2) The device does not activate;

(3) The device is used for a test after the expiration date printed on its package;

(b) With respect to any test conducted on a non-evidential alcohol testing device—

(1) The STT has failed to note on the remarks section of the form that the employee has failed or refused to sign the form following the recording on the form of the test result; or

(2) The procedures of § 40.101(d) are not followed.

§ 40.109 Availability and disclosure of alcohol testing information about individual employees.

The provisions of § 40.81 apply to records of non-evidential alcohol screening tests.

§ 40.111 Maintenance and disclosure of records concerning non-evidential alcohol screening test devices and screening test technicians.

Records concerning STTs and non-evidential testing devices shall be maintained and disclosed following the same requirements applicable to BATs and EBTs under § 40.81 of this Part.

5. A new Appendix C to Part 40 is proposed to be added, to read as follows:

Appendix C to Part 40—The Saliva Alcohol Testing Form

[A printed version of the saliva alcohol testing form was not ready at the time of the publication of this notice. However, for the information of commenters, the form is in most respects identical to the existing breath alcohol testing form. Differences are as follows: References to the "Breath Alcohol Testing Form" and the "Breath Alcohol Technician" would be replaced by references to the "Saliva Alcohol Testing Form" and "Screening Test Technician," respectively. References to "breath alcohol testing" would be replaced by references to "saliva alcohol testing." In Block 3, the line directing confirmation test results to be attached to the back of the form would be deleted, as would the space for attaching such results on the back of the form. Also in Block 3, the words "Testing Device Serial Number" would be deleted and the words "Device Expiration Date" substituted.]

[FR Doc 95-1188 Filed 1-12-95, 3:50 pm]

BILLING CODE 4910-62-P